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10/538,239	01/03/2006	Adam Alexander Tebbutt	1171/43247/160-PCT-US	3586
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CLARK HILL, PLC			EXAMINER	
150 NORTH MICHIGAN AVENUE			OSTRUP, CLINTON T	
SUITE 2700				
CHICAGO, IL 60601			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mkitz@clarkhill.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,239	<b>Applicant(s)</b> TEBBUTT ET AL.
	<b>Examiner</b> CLINTON OSTRUP	<b>Art Unit</b> 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 28 May 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 68,69,71,72,75-87 and 89-91 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 68,69,71,72,75-87 and 89-91 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 03 June 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is in response to the amendment filed May 28, 2010. As directed by the amendment, claims 68-69, 71-72, 75-87, and 89-90 have been amended and claim 91 has been added. Claims 1-67, 70, 73-74, and 88 are cancelled. Thus, claims 68-69, 71-72, 75-87, and 89-91 are pending in this application.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 68-69, 77, 81 & 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) and further in view of Dietz (5,005,571).

Regarding claim 68, Feinberg discloses an interface (figure 3) for the delivery of gases (air) from a source (13) to a user (human), comprising: an elbow connector (11) capable of receiving gases from the source (13); an outer flap (10) adapted to conform to the user's mouth (as shown in figure 1) and in fluid connection (air travels through 11 to 22 and 18 which are in fluid communication with 10) with said elbow connector (11), said outer flap (10) providing a **substantial** seal about the outside of the user's mouth (see figure 1) and capable of delivering said gases (air) from said elbow connector (11) to the user's oral passage (via 18); and nasal cannula (24) sealing in each of the nares of the user, said nasal cannula (24) attached to (via 25) and in fluid connection (air enters 25 to 24) with one of said outer flap (10) and said elbow connector (11) such that

said nasal cannula is capable of delivering gases (air) to the user's nares. See: page 1, col. 1, line 55 - page 1, col. 2, lie 97; page 2, col. 1, lines 6-24; and figures 1 & 3.

However, Feinberg lacks the outer flap defining a gases space around the user's mouth.

Dietz teaches a mask (figures 1 & 2) with an outer flap (2) defining a gases space around a user's mouth with a nasal cannula providing air to a user. See: col. 5, line 64 - col. 6, line and figures 1 & 2.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the outer flap of the breathing apparatus disclosed by Feinberg, to provide a gases space around the user's mouth, as taught by Dietz, in order to obtain a breathing device that seals around the face of a user thereby providing a device that would provide respiratory gasses to the other breathing passages if one passage becomes occluded.

Regarding claim 69, Feinberg discloses an elbow connector (11) that is substantially L-shaped, where one end (part of 11 connecting 24 & 18) of the L-shaped elbow connector (11) is connected in use to said nasal cannula (24) and said outer flap (10), while the other end (part of 11 connected to 1) of the L-shaped nasal connector is adapted to receive said gases for delivery to the user. See: figures 1 & 3.

Regarding claim 77, Feinberg discloses an interface (figure 3) with the nasal cannula that comprises a pair (24) of nasal prongs.

Regarding claim 81, the combined references discloses an interface (figure 3 of Feinberg) with an outer flap (modified 10 of Feinberg with 2 of Dietz) that includes a

tubular passageway (for connecting 11 to 12 of Feinberg) extending through said outer flap (modified 10 of Feinberg with 2 of Dietz), said tubular passageway in fluid communication with said elbow connector (11 of Feinberg) to deliver gases from said elbow connector (11 of Feinberg) to the user's mouth. See: page 1, col. 1, line 55 - col. 2, line 64 and figures 1 & 3 of Feinberg and figures 1 &2 of Dietz.

Regarding claim 84, Freinberg discloses an interface (figure 3) further including a vestibular shield (15) connected to said tubular passageway (for connecting 11 to 12), said vestibular shield (15) being disposed in use within a user's mouth vestibule. See: page 1, col. 2, lines 75-80.

4. Claims 71 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) in view of Dietz (5,005,571) and further in view of Daniell et al., (EP 0845277 A2).

The combined references disclose a patient interface (figure 3) for the delivery of gases (air) from a source (13) to a user (human), comprising: an elbow connector (11) capable of receiving gases from the source (13) ; an outer flap (10) adapted to conform to the user's mouth (as shown in figure 1) and in fluid connection (air travels through 11 to 22 and 18 which are in fluid communication with 10) with said elbow connector (11), said outer flap (10) providing a **substantial** seal about the outside of the user's mouth (see figure 1) and capable of delivering said gases (air) from said elbow connector (11) to the user's oral passage (via 18); and nasal cannula (24) sealing in each of the nares of the user, said nasal cannula (24) attached to (via 25) and in fluid connection (air enters 25 to 24) with one of said outer flap (10) and said elbow connector (11) such that

said nasal cannula is capable of delivering gases (air) to the user's nares. See: page 1, col. 1, line 55 - page 1, col. 2, lie 97; page 2, col. 1, lines 6-24; and figures 1 & 3.

However, the combined references lack the elbow connector having an outlet vent to allow diffusion of the user's exhaled gas.

Daniell teaches a swivel type elbow connection with an outlet vent (37 of figure 8) that allows a patient to exhale through the nasal passage or through the mouth. See: col. 8, lines 22-45.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted elbow connector disclosed by Feinberg with the swivel elbow connector with an outlet, as taught by Daniell in order to obtain a gas delivery apparatus that would allow a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires.

Regarding claim 91, Daniell teaches a breathing circuit (figures 1 & 2) defining a gasses pathway connected to and in fluid communication with a gases source and the interface of the combined references is connected to and in fluid communication with the breathing circuit.

5. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) in view of Dietz (5,005,571), as applied to claims 68 and 69 above, and further in view of Ging et al., (2003/0196662).

The combined references disclose all the limitations of claim 72 except an elbow connector comprises a plurality of apertures in the apex of the L-shape of the elbow connector with the apertures adapted to vent gases exhaled from the user.

Ging teaches an elbow connection (360) assembly with a vent cover (figures 20-22d) that have a plurality of apertures (390) in the apex of an L-shape of the elbow connector and the apertures adapted to vent gases exhaled from the user. See: figures 20-22d and [0166].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to used a plurality of outlet apertures, as taught by Ging, instead of a single outlet aperture, as disclosed by Daniell in order to form a gas delivery device that allows a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires that would continue to function even if one of the apertures becomes blocked or closed.

6. Claims 75-76, 78, & 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) in view of Dietz (5,005,571) and further in view of Goldstein (6,012,455).

However, the combined references lack the extension mechanism adapted to allow the nasal cannula to adjustably extend from the elbow connector or outer flap.

Goldstein teaches a nasal cannula that includes an extension mechanism (100 & 102 and col. 5, lines 38-43) that would allow the nasal cannula to adjustably extend from the elbow connector (11 of Feinberg) or said outer flap (10 of Feinberg).

It would have obvious to one having ordinary skill in the art at the time the invention was made to have modified the nasal cannula disclosed by the combined references by utilizing nasal cannula members with an extension mechanism, as taught by Goldstein, in order to form a mouthpiece with nasal cannulas that can be easily adjusted to provide a comfortable fit to a user.

Regarding claim 76, Goldstein teaches the extension mechanism as a series of bellow-like corrugations (figure 14) on the nasal cannula that allows the length of said nasal cannula to be adjusted. See: col. 5, lines 38-43.

Regarding claim 78 and 90, the nasal cannula taught by Goldstein is capable of detaching (via disconnecting tubes) from the elbow connector (11 of Feinberg) and/or the said outer flap (10 of Feinberg), which would allow for different sized nasal cannula to be connected to the said elbow connector (11 of Feinberg) and/or the outer flap (10 of Feinberg).

7. Claims 79, 80, and 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) in view of Dietz (5,005,571) as applied to claim 68 and 81 above, and further in view of Robertson et al (EP 1075848 A2).

The combined references disclose all the limitations of claim 79 and 83, except the nasal cannula being made of silicone.

Robertson discloses an interface with an elbow connector that includes a swivelable joint ([0025] of Robertson) that would allow the elbow connector (11 of Feinberg) to swivel relative to the nasal cannula (24 of Feinberg) and said outer flap (10 of Feinberg). Robertson also discloses forming a mouthpiece made of silicone [0026]

and it would have been obvious to one having ordinary skill in the art to have formed the entire airway device taught by the combined references of the same material because it has been held that the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Regarding claim 80, Robertson discloses an outer flap (300) that has a lip (306) [0030] or (61) [0020]) extending around its perimeter to assist in sealing of said outer flap against the user's face and it would have been obvious to one having ordinary skill in the art to have modified the flap (10 of Feinberg) to have an outer lip as taught by Robertson in order to provide a user with a good seal.

Regarding claim 82, Robertson discloses a tubular passageway (304) that contains two outlets (302 & 303) to direct gases flow around the sides of the user's mouth as gases flow out of said tubular passageway and into the user's mouth and it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the gas passageway disclosed by Freinberg, by using a secondary passageway, as taught by Robertson in order to ensure proper delivery of air to a user even in the event that of occlusion of one outlet.

8. Claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) and further in view of Goldstein (6,012,455).

Feinberg discloses a patient interface (figure 3) for the delivery of gases (air) from a source (13) to a user (human), comprising: an elbow connector (11) capable of receiving gases from the source (13); an outer flap (10) adapted to conform to the

user's mouth (as shown in figure 1) and in fluid connection (air travels through 11 to 22 and 18 which are in fluid communication with 10) with said elbow connector (11), said outer flap (10) providing a **substantial** seal about the outside of the user's mouth (see figure 1) and capable of delivering said gases (air) from said elbow connector (11) to the user's oral passage (via 18); and nasal cannula (24) sealing in each of the nares of the user, said nasal cannula (24) attached to (via 25) and in fluid connection (air enters 25 to 24) with one of said outer flap (10) and said elbow connector (11) such that said nasal cannula is capable of delivering gases (air) to the user's nares. See: page 1, col. 1, line 55 - page 1, col. 2, lie 97; page 2, col. 1, lines 6-24; and figures 1 & 3.

However, Feinberg lacks the extension mechanism adapted to allow the nasal cannula to adjustably extend from the elbow connector or outer flap.

Goldstein teaches a nasal cannula that includes an extension mechanism (100 & 102 and col. 5, lines 38-43) that would allow the nasal cannula to adjustably extend from the elbow connector (11 of Feinberg) or said outer flap (10 of Feinberg).

It would have obvious to one having ordinary skill in the art at the time the invention was made to have modified the nasal cannula disclosed by Feinberg by utilizing nasal cannula members with an extension mechanism, as taught by Goldstein, in order to form a mouthpiece with nasal cannulas that can be easily adjusted to provide a comfortable fit to a user.

Regarding claim 86, Goldstein teaches the extension mechanism as a series of bellow-like corrugations (figure 14) on the nasal cannula that allows the length of said nasal cannula to be adjusted. See: col. 5, lines 38-43.

Regarding claim 87, the nasal cannula taught by Goldstein is capable of detaching (via disconnecting tubes) from the elbow connector (11 of Feinberg) and/or the said outer flap (10 of Feinberg), which would allow for different sized nasal cannula to be connected to the said elbow connector (11 of Feinberg) and/or the outer flap (10 of Feinberg).

9. Claim 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) in view of Robertson et al (EP 1075848 A2) and further in view of Daniell et al., (EP 0845277 A2).

The combined references disclose a patient interface (figure 3) for the delivery of gases (air) from a source (13) to a user (human), comprising: an elbow connector (11) capable of receiving gases from the source (13); an outer flap (10) adapted to conform to the user's mouth (as shown in figure 1) and in fluid connection (air travels through 11 to 22 and 18 which are in fluid communication with 10) with said elbow connector (11), said outer flap (10) providing a **substantial** seal about the outside of the user's mouth (see figure 1) and capable of delivering said gases (air) from said elbow connector (11) to the user's oral passage (via 18); and nasal cannula (24) sealing in each of the nares of the user, said nasal cannula (24) attached to (via 25) and in fluid connection (air enters 25 to 24) with one of said outer flap (10) and said elbow connector (11) such that said nasal cannula is capable of delivering gases (air) to the user's nares. See: page 1, col. 1, line 55 - page 1, col. 2, lie 97; page 2, col. 1, lines 6-24; and figures 1 & 3.

However, the combined references lack the elbow connector having an outlet vent to allow diffusion of the user's exhaled gas.

Daniell teaches a swivel type elbow connection with an outlet vent (37 of figure 8) that allows a patient to exhale through the nasal passage or through the mouth. See: col. 8, lines 22-45.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the swivel elbow connector disclosed by Robertson with the swivel elbow connector with an outlet, as taught by Daniell in order to obtain a gas delivery apparatus that would allow a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires.

***Response to Arguments***

10. Applicant's arguments filed May 28, 2010, with respect to claims 68-69, 71-72, 75-84 and 90 have been considered but are moot in view of the new ground(s) of rejection.

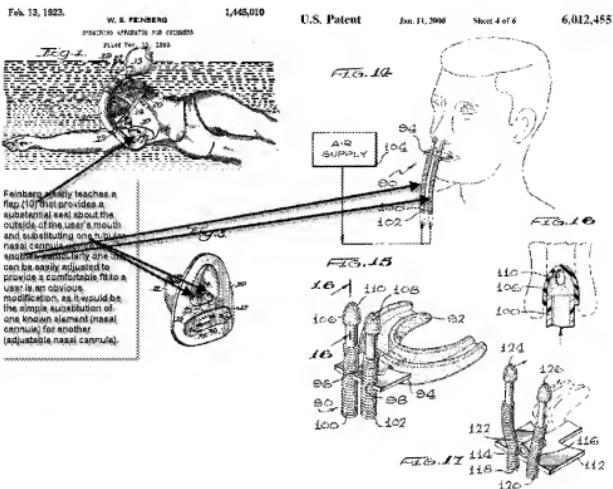
11. Applicant's arguments filed May 28, 2010, with respect to claims 85-87 and 89 have been fully considered but they are not persuasive.

12. Regarding claims 85-87, applicant argues that the combination of Feinberg and Goldstein does not result in a mask with nasal cannula having an adjustment mechanism that allows the cannula to adjustably extend and that the combination will not result in a mask that provides a **substantial** seal about the outside of the user's mouth.

First, Feinberg clearly teaches a flap (10) that provides a **substantial** seal about the outside of the user's mouth and substituting one tubular nasal cannula device for

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another, particularly one that can be easily adjusted to provide a comfortable fit to a user is an obvious modification, as it would be the simple substitution of one known element (nasal cannula) for another (adjustable nasal cannula).



13. Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. 103(a). Ex Parte Smith, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007) (citing KSR v. Teleflex, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements

yields predictable results; absent evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a). Ex Parte Smith, 83 USPQ.2d at 1518-19 (BPAI, 2007) (citing KSR, 127 S.Ct. at 1740, 82 USPQ2d at 1396. Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

14. Regarding claim 89, applicant's assertion that Feinberg discloses a swimming mask and that it cannot be obvious to put vent holes onto the elbow of the swim mask of Feinberg because placing vent holes on the elbow of that mask would place the user at grave risk of drowning has not been found convincing because the apparatus disclosed by Feinberg is a breathing apparatus and one having ordinary skill in the art would readily recognize that a tubular passage connected to a mask could be used to deliver respiratory gases to the breathing passages of a swimmer or a patient with sleep disorders via continuous positive airway pressure as particularly taught by both Roberson and Daniell.

15. Therefore, applicant's arguments have not been found convincing and the said rejections have been MAINTAINED.

16. In response to applicant's amendment to the preamble wherein "mouthpiece" has been substituted with "patient interface", the recitation of the "patient interface" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

17. Moreover, it has been held that if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

### ***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Illing teaches an oronasal respirator and Davidson et al. (7,658,189) & Davidson et al. (7,708,017) both disclose compact oronasal respiratory gas delivery systems.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/  
Examiner, Art Unit 3771

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772